UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/580,922	03/15/2007	Barry Slobedman	SPRUS61.001APC	8791

20995 7590 05/23/2011
KNOBBE MARTENS OLSON & BEAR LLP
2040 MAIN STREET
FOURTEENTH FLOOR
IRVINE, CA 92614

EXAMINER	
STOICA, ELLY GERALD	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
05/23/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
efiling@kmob.com
eOAPilot@kmob.com

Office Action Summary	Application No.	Applicant(s)	
	10/580,922	SLOBEDMAN ET AL.	
	Examiner	Art Unit	
	ELLY-GERALD STOICA	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 May 2011*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-8,24,28,30,40-44,52 and 58-61* is/are pending in the application.

4a) Of the above claim(s) *40-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-8,24,28,30,52 and 59-61* is/are rejected.

7)☒ Claim(s) *58* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/04/2011 has been entered. Claims 1, 6-8, 24, 28, 30, 40-44, 52 and 58-61 are pending. Claims 40-44 remain withdrawn for reasons of record. Claims 1, 6-8, 24, 28, 30, 52 and 58-61 are currently examined.

Claim Objections

2. Claim 61 is objected to because of the following informalities: the word "performed" should be inserted in line 1 after "is". Appropriate correction is required. Even though Applicant mentioned in the remarks that the informality was corrected, it is apparent that the informality is still present.

Claim interpretation

3. In the broadest reasonable interpretation, the isolated nucleic acid claimed in claim 1 comprises a sequence as defined in SEQ ID NO: 1. Since the product **comprises** SEQ ID NO: 1, it is submitted that an isolated nucleic acid comprising the

nucleotides of SEQ ID NO:1, not necessarily uninterrupted, are within the scope of the claim.

Claim Rejections - 35 USC § 112, 4th paragraph

4. The following is a quotation of the fourth paragraph of 35 U.S.C. 112:

> Subject to the following paragraph, a claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

5. Claim 60 is rejected under 35 U.S.C. 112, fourth paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim.

See the "Supplementary Examination Guidelines for Determining Compliance With 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications" (Federal Register, Vol. 76, No. 27, Wednesday, February 9, 2011), pg 7166, section "5. Dependent Claims", which states that "If the dependent claim does not comply the with the requirements of § 112, ¶4, the examiner should reject the dependent claim under § 112, ¶4 as unpatentable rather than objecting to the claim" and "a dependent claim must be rejected under § 112, ¶4 if it omits an element from the claim upon which it depends or it fails to add a limitation to the claim upon which it depends".

Specifically, dependent claim 60 recites: "The method of claim 59, wherein said detecting utilizes a fragment of a nucleic acid as defined in SEQ ID NO: 1, wherein the fragment comprises a sequence as defined in SEQ ID NO: 4 **or** SEQ ID NO: 9."

However, parent claim 1 already limits the fragment to a fragment of SEQ ID NO: 1, wherein the fragment is less than 150 nucleotides in length and comprises both SEQ ID NO: 4 **and** SEQ ID NO: 9.

Therefore, dependent claim 60 is of improper dependent form because it fails to further limit the subject matter of parent claim 1.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

7. Claims 1 and 6-8 remain rejected under 35 U.S.C. 102(e) as being anticipated by Liu et al. (U.S. Pat. No. 7,407,744- filed 07/23/2004-cited previously).

Liu et al. teach 45 viral ORFs essential for viral replication and characterized 115 growth-dispensable viral genes of the human CMV (col. 2, lines18-24). Sequences of the gene are used in the development of vectors. Protein products of the genes are useful as targets for drug design, as targets for immunological agents, and the like. The mutant HCMV are useful in a number of screening methods. Screening methods include the growth of HCMV in different human cell lines (Col. 2, lines 45-62). The SEQ ID NO: 1 of the Liu et al. comprises fragments of SEQ ID NO: 1 of the instant

Application (and also SEQ ID NO: 4 and 9 of the instant Application) and thus it is considered that anticipates the claims 1 and 6-8 of the instant Application.

```
RESULT 1
US-10-897-508-1
; Sequence 1, Application US/10897508
; Patent No. 7407744
; GENERAL INFORMATION:
;  APPLICANT: Fenyong Liu
;  APPLICANT:  Walter Dunn
;  APPLICANT:  CASSIE CHOU
;  TITLE OF INVENTION: CYTOMEGALOVIRUS GENE FUNCTION AND
;  TITLE OF INVENTION:  METHODS FOR DEVELOPING ANTIVIRALS, ANTI-CMV VACCINES,
AND
;  TITLE OF INVENTION:  CMV-BASED VECTORS
;  FILE REFERENCE: BERK-025
;  CURRENT APPLICATION NUMBER: US/10/897,508
;  CURRENT FILING DATE:  2004-07-23
;  PRIOR APPLICATION NUMBER: 60/490,200
;  PRIOR FILING DATE: 2003-07-25
;  NUMBER OF SEQ ID NOS: 1
;  SOFTWARE: FastSEQ for Windows Version 4.0
; SEQ ID NO 1
;   LENGTH: 218802
;   TYPE: DNA
;   ORGANISM: cytomegalovirus
;   FEATURE:
;   NAME/KEY: misc_feature
;   LOCATION: 19769
;   OTHER INFORMATION: n = A,T,C or G
US-10-897-508-1

  Query Match             87.8%;  Score 654.6;  DB 7;  Length 218802;
  Best Local Similarity   90.3%;
  Matches  741;  Conservative    2;  Mismatches    2;  Indels   76;  Gaps
1;

Qy      1 CATAAAGGACCACCTACCTGGGACGCGCAGTTGGGCGGCGGACTGGGACGGCATGCTGCG 60
          ||||||||||||||||||||||||||||||||||||||||||||| ||||||||||||
Db 149288 CATAAAGGACCACCTACCTGGGACGCGCAGTTGGGCGGCGGACTGGGGCGGCATGCTGCG 149347

Qy     61 GTGATGCTGTCGGTGATGGTCTCTTCCTCTCTGGTCCTGATCGTCTTTTTTCTAGGCGCT 120
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 149348 GTGATGCTGTCGGTGATGGTCTCTTCCTCTCTGGTCCTGATCGTCTTTTTTCTAGGCGCT 149407

Qy    121 TCCGAGGAGGCGAAGCCGGCGACGACGACGACGATAAAGAATACAAAGCCGCAGTGTCGT 180
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 149408 TCCGAGGAGGCGAAGCCGGCGACGACGACGACGATAAAGAATACAAAGCCGCAGTGTCGT 149467

Qy    181 CCAGAGGATTACGCGACCAGATTGCAAGATCTCCGCGTCACCTTTCATCGAGTAAAACCT 240
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db 149468 CCAGAGGATTACGCGACCAGATTGCAAGATCTCCGCGTCACCTTTCATCGAGTAAAACCT 149527
```

```
Qy     241 ACGTT---------------------------------------------------- 245
           |||||
Db  149528 ACGTTGGTAGGTCACGTAGGTACGGTTTATTGTGACGGTCTTTCTTTTCCGCGTGTCGGG 149587

Qy     246 --------------------GCAACGTGAGGACGACTACTCCGTGTGGCTCGACGGTAC 284
                                  ||||||||||||||||||||||||||||||||||||
Db  149588 TGACGTAGTTTTCCTCTTGTAGCAACGTGAGGACGACTACTCCGTGTGGCTCGACGGTAC 149647

Qy     285 GGTGGTCAAAGGCTGTTGGGGATGCAGCGTCATGGACTGGTTGTTGAGGCGGTATCTGGA 344
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  149648 GGTGGTCAAAGGCTGTTGGGGATGCAGCGTCATGGACTGGTTGTTGAGGCGGTATCTGGA 149707

Qy     345 GATCGTGTTCCCCGCAGGCGACCACGTCTATCCCGGACTCAAGACGGAATTGCATAGTAT 404
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  149708 GATCGTGTTCCCCGCAGGCGACCACGTCTATCCCGGACTCAAGACGGAATTGCATAGTAT 149767

Qy     405 GCGCTCGACGCTAGAATCCATCTACAAAGACATGCGGCAATGCGTAAGTGTCTCTGTGGC 464
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  149768 GCGCTCGACGCTAGAATCCATCTACAAAGACATGCGGCAATGCGTAAGTGTCTCTGTGGC 149827

Qy     465 GGCGCTGTCCGCACAGAGGTAACAACGTGTTCATAGCACGCTGTTTTACTTTTGTCGGGC 524
           |||||||||||| ||||||||||||||||||||||||||||||||||||||||||||||
Db  149828 GGCGCTGTCCGCGCAGAGGTAACAACGTGTTCATAGCACGCTGTTTTACTTTTGTCGGGC 149887

Qy     525 TCCCAGCCTCTGTTAGGTTGCGGAGATAAGTCCGTGATTAGTCGGCTGTCTCAGGAGGCG 584
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  149888 TCCCAGCCTCTGTTAGGTTGCGGAGATAAGTCCGTGATTAGTCGGCTGTCTCAGGAGGCG 149947

Qy     585 GAAAGGAAATCGGATAACGGCACGCGGAAAGGTCTCAGCGAGTTGGACACGTTGTTTAGC 644
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  149948 GAAAGGAAATCGGATAACGGCACGCGGAAAGGTCTCAGCGAGTTGGACACGTTGTTTAGC 150007

Qy     645 CGTCTCGAAGAGTATCTGCACTCGAGAAAGTAGCGTTGCGATTTGCAGTCCGCTCCGGTG 704
           ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db  150008 CGTCTCGAAGAGTATCTGCACTCGAGAAAGTAGCGTTGCGATTTGCAGTCCGCTCCGGTG 150067

Qy     705 TCGTTCACCCAGTTACTTTAATAAACGTACTGTTTAACCRB 745
           |||||||||||||||||||||||||||||||||||||::
Db  150068 TCGTTCACCCAGTTACTTTAATAAACGTACTGTTTAACCAC 150108
```

On page 6 of the Remarks Applicant argues that Liu et al. do not disclose a sequence that is less than 150 nucleotides in length and comprises SEQ ID NO: 4 and SEQ ID NO: 9 as presently claimed. The arguments were carefully considered but not found persuasive because as submitted supra, claim 1 is drawn to an isolated nucleic acid comprising a sequence as defined in SEQ ID NO:1 **or** a fragment thereof, wherein

the fragment is less than 150 nucleotides in length and comprises SEQ ID NO: 4 and SEQ ID NO: 9. Since the polynucleotide comprises SEQ ID NO:1 then the SEQID NO:1 of Liu also comprises it.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 24, 28, 30, 52 and 59-61 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (U.S. Pat. No. 7,407,744- filed 07/23/2004) in view of Williams et al. (U.S. Pat. No. 7,361,460- filed 04/11/2003).

The claims are drawn to a method for screening a subject for infection by a virus of the herpesvirideae group, the method comprising: (a) obtaining a biological sample from said subject; (b) contacting said biological sample from said subject with an isolated nucleic acid sequence of claim 1; and (c) detecting the presence or absence of hybridization between a nucleic acid in said biological sample and the isolated nucleic acid of claim 1, wherein the presence of hybridization indicates infection. Further limitations are added to the isolated nucleic acid used in terms of length. The detection method may also be PCR based using primers selected from SEQ ID NO: SEQ ID NO:1. Also claimed is a kit comprising an isolated nucleic acid and reagents for hybridization.

The teachings of Liu et al. were presented supra. Even though they envision the use of the nucleic acid as screening tools, they are silent about the actual methodology or about a kit that uses them.

Williams et al. teach accurate, sensitive, and efficient methods for molecular diagnosis of human papillomavirus (HPV)-based disease, where the method improves the accuracy and reliability of diagnostic and prognostic assessments of HPV-based disease (abstract). One of the methods for the diagnosis of HPV infection comprises a primary screen for detecting HPV nucleic acids by hybridization with DNA or RNA

probes directed against specific types of HPV. Several different HPV hybridization methodologies may be used including, but not limited to, Southern blot, Dot blot, Slot blot, and in situ hybridization. Other non-limiting examples of techniques for detecting HPV nucleic acids include, polymerase chain reaction (PCR) including both low stringency (broadly cross-reactive) and high stringency (type-specific) methods. PCR-based methods have been used successfully for the detection and typing of genital HPV genotypes in clinical specimens, such as cervical swabs or scrapes, saline cervicovaginal lavages, frozen biopsies, and formalin-fixed paraffin-embedded tissues (col.6, lines 8-35). Also taught are kits for diagnosing the HPV-based disease (col. 4, lines 17-19).

It would have been obvious for a person of ordinary skill in the art at the time that the invention was made to have used the fragments of Liu et al. (which comprise SEQ ID NO: 1 of the instant Application) to diagnose a viral infections by the procedures described by Williams et al. with a reasonable expectation of success. This is because Liu et al. suggested the use of the fragments and Williams et al. is just an example of an application of known techniques to diagnose diseases based on nucleic acid detection and possible using the reagents in a kit. A person of ordinary skill in the art is always motivated to pursue the known options within her or his technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

On page 6 of the Remarks Applicant argues that, due to the amendments to the claims, the rejection no longer applies. The arguments were carefully considered but not

found persuasive because as presented above, one of the interpretations of the claims comprises SEQ ID NO:1 and therefore the rejection stands.

Conclusion

12. Claim 58 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

13. Claims 1, 6-8, 24, 28, 30, 52 and 59-61 are not allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLY-GERALD STOICA whose telephone number is (571)272-9941. The examiner can normally be reached on 9:00-18:30 M-Th and 9:00-18:30 alternate F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey J. Stucker can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elly-Gerald Stoica/
Primary Examiner, Art Unit 1647